



ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2019-0531; FRL-10017-27]

Penthiopyrad; Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes a tolerance for residues of penthiopyrad in or on persimmon. Mitsui Chemicals Agro, Inc., % Landis International, Inc. requested this tolerance under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective [INSERT DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]. Objections and requests for hearings must be received on or before [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*], and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

ADDRESSES: The docket for this action, identified by docket identification (ID) number EPA-HQ-OPP-2019-0531, is available at <http://www.regulations.gov> or at the Office of Pesticide Programs Regulatory Public Docket (OPP Docket) in the Environmental Protection Agency Docket Center (EPA/DC), West William Jefferson Clinton Bldg., Rm. 3334, 1301 Constitution Ave., NW., Washington, DC 20460-0001. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566-1744, and the telephone number for the OPP Docket is (703) 305-5805. Please review the visitor instructions and additional information about the docket available at <http://www.epa.gov/dockets>.

FOR FURTHER INFORMATION CONTACT: Marietta Echeverria, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania

Ave., NW., Washington, DC 20460-0001; main telephone number: (703) 305-7090; email address: *RDFRNotices@epa.gov*.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this action apply to me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

B. How can I get electronic access to other related information?

You may access a frequently updated electronic version of EPA's tolerance regulations at 40 CFR part 180 through the Government Publishing Office's e-CFR site at http://www.ecfr.gov/cgi-bin/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab_02.tpl.

C. How can I file an objection or hearing request?

Under FFDCA section 408(g), 21 U.S.C. 346a, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA-HQ-OPP-2019-0531 in the subject line on the first page of your submission. All objections and requests for a hearing must be in writing and must be received by the Hearing Clerk on or before [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL*

REGISTER]. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing (excluding any Confidential Business Information (CBI)) for inclusion in the public docket. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit the non-CBI copy of your objection or hearing request, identified by docket ID number EPA-HQ-OPP-2019-0531, by one of the following methods:

- *Federal eRulemaking Portal*: <http://www.regulations.gov>. Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be CBI or other information whose disclosure is restricted by statute.

- *Mail*: OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), (28221T), 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001.

- *Hand Delivery*: To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at <http://www.epa.gov/dockets/contacts.html>.

Due to the public health concerns related to COVID-19, the EPA Docket Center (EPA/DC) and Reading Room is closed to visitors with limited exceptions. The staff continues to provide remote customer service via email, phone, and webform. For the latest status information on EPA/DC services and docket access, visit <https://www.epa.gov/dockets>.

II. Summary of Petitioned-For Tolerance

In the *Federal Register* of June 24, 2020 (85 FR 37806) (FRL-10010-82), EPA issued a document pursuant to FFDCA section 408(d)(3), 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 9E8773) by Mitsui Chemicals Agro, Inc. % Landis International, Inc., 3185 Madison Highway, P.O. Box 5126, Valdosta, GA 31603-5126. The petition requested that 40 CFR 180.658 be amended by establishing a tolerance for residues of the fungicide, Penthiopyrad (*N*-[2-(1,3-dimethylbutyl)-3-thienyl]-1-methyl-3-(trifluoromethyl)-1*H*-pyrazole-4-

carboxamide) in or on persimmon, at 3.0 parts per million (ppm). That document referenced a summary of the petition prepared by Mitsui Chemicals Agro, Inc. % Landis International, Inc., the registrant, which is available in the docket for this action, docket ID number EPA-HQ-OPP-2019-0531, at <http://www.regulations.gov>. There were no comments received in response to the notice of filing. EPA is setting a tolerance of 3 ppm in persimmon, instead of the petitioner-proposed tolerance value of 3.0 ppm. This change is explained in Unit IV.C.

III. Aggregate Risk Assessment and Determination of Safety

A. Statutory Background

Section 408(b)(2)(A)(i) of the FFDCA allows EPA to establish a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is “safe.” Section 408(b)(2)(A)(ii) of FFDCA defines “safe” to mean that “there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.” This includes exposure through drinking water and in residential settings but does not include occupational exposure. Section 408(b)(2)(C) of FFDCA requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to “ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue....”

Consistent with FFDCA section 408(b)(2)(D) and the factors specified therein, EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure for penthiopyrad, including exposure resulting from the tolerance established by this action. EPA's assessment of exposures and risks associated with penthiopyrad follows.

B. Aggregate Risk Assessment

In an effort to streamline *Federal Register* publications, EPA is directing readers to certain sections of *Federal Register* notifications for previous tolerance rulemakings for the same

pesticide that contain information that has not changed in the current risk assessment. To that end, on June 6, 2019, EPA published in the *Federal Register* a final rule establishing a tolerance for residues of penthiopyrad in or on multiple commodities based on the Agency's conclusion that aggregate exposure to penthiopyrad is safe for the general population, including infants and children. *See* 84 FR 26352 (FRL-9994-08). Please refer to the following sections of the previous tolerance rulemaking that contain information that has remained the same under the current risk assessment for this rulemaking: Units III.A (Toxicological Profile); III.B (Toxicological Points of Departure/Levels of Concern); III.C (Exposure Assessment), except as explained in the next paragraph; and III.D (Safety Factor for Infants and Children).

Updates to exposure assessment. The Agency conducted an updated risk assessment to evaluate exposure to residues of penthiopyrad on persimmon. EPA's acute and chronic dietary (food and drinking water) exposure assessments have been updated to include the additional exposure from use of penthiopyrad on persimmon. As to residue levels in food, the dietary exposure assessments are based on tolerance-level residues and assumed 100 percent crop treated (PCT). There will be no U.S. registrations for use of penthiopyrad on persimmon, and there is no proposed new residential use. Therefore, EPA's assessments of dietary exposure from drinking water and non-dietary (*i.e.*, residential) exposure, as well as cancer classification and cumulative effects from substances with a common mechanism of toxicity, have not changed and are described in the previous tolerance rulemaking.

Assessment of aggregate risks. Acute aggregate risk estimates are equal to acute dietary (food and drinking water) risk estimates, which are below the Agency's level of concern of 100% of the acute population adjusted dose (aPAD): the exposure estimate is 20% of the aPAD at the 95th percentile of exposure for infants less than 1 year old, which is the population subgroup with the highest exposure estimate. Chronic aggregate risk estimates are equal to chronic dietary (food and drinking water) risk estimates, which are below the Agency's level of concern of 100% of the chronic population adjusted dose (cPAD): the exposure estimate is 28%

of the cPAD for infants less than 1 year old, which is the population subgroup with the highest exposure estimate. Short-term aggregate risk estimates are equal to the most conservative residential exposure estimates plus chronic dietary exposure estimates (considered to be background dietary exposure). For adults, the most conservative residential exposure estimate is dermal exposure through high contact lawn activity, with a margin of exposure (MOE) above the Agency's level of concern of 100 (MOE = 560). For children, the most conservative residential exposure estimate is combined dermal and incidental oral exposure through high contact lawn activity, with an MOE above the Agency's level of concern of 100 (MOE = 270). Moreover, the children 1 to less than 2 years old population subgroup was chosen for the short-term aggregate risk estimate for children, since the exposure estimate for this subgroup is protective for all other children subpopulations. Considering both the chronic dietary (food and drinking water) exposures and the high contact lawn activity residential exposures for both adults and children, EPA has concluded the short-term aggregate MOEs are 440 and 220 for adults and children, respectively, which are above the level of concern of 100 and therefore are not of concern.

C. Determination of Safety

Therefore, based on the risk assessments and information described above, EPA concludes there is a reasonable certainty that no harm will result to the general population, or to infants and children, from aggregate exposure to penthiopyrad residues. More detailed information on the subject action to establish a tolerance in or on persimmon can be found in the document entitled, "Penthiopyrad. Human Health Risk Assessment for the Proposed Tolerance Without a U.S. Registration on Persimmon." dated 12/14/2020 at www.regulations.gov, under docket ID number EPA-HQ-OPP-2019-0531.

IV. Other Considerations

A. Analytical Enforcement Methodology

Adequate enforcement methodology (a liquid chromatography-tandem mass spectrometry (LC/MS/MS) method known as Method CEM 3399-001) is available to enforce

penthiopyrad tolerances. The method may be requested from: Chief, Analytical Chemistry Branch, Environmental Science Center, 701 Mapes Rd., Ft. Meade, MD 20755-5350; telephone number: (410) 305-2905; email address: *residuemethods@epa.gov*.

B. International Residue Limits

In making its tolerance decisions, EPA seeks to harmonize U.S. tolerances with international standards whenever possible, consistent with U.S. food safety standards and agricultural practices. EPA considers the international maximum residue limits (MRLs) established by the Codex Alimentarius Commission (Codex), as required by FFDCA section 408(b)(4). Codex is a joint United Nations Food and Agriculture Organization/World Health Organization food standards program, and it is recognized as an international food safety standards-setting organization in trade agreements to which the United States is a party. EPA may establish a tolerance that is different from a Codex MRL; however, FFDCA section 408(b)(4) requires that EPA explain the reasons for departing from the Codex level.

The established Codex MRL for penthiopyrad in persimmons is 0.4 mg/kg. The 3 ppm tolerance being established is harmonized with the existing Japanese MRL of 3 ppm instead, which is consistent with the tolerance value requested by the petitioner. According to the registrant, the locations of the field trials for residue data reflect the primary importation of persimmon from Japan. The registrant cited USDA Economic Research Service data indicating that Spain, Israel, and Chile are the only countries with >5% imports of persimmons into the United States. The registrant indicated that penthiopyrad is registered in Spain and Israel but not on persimmon and that penthiopyrad is not registered in Chile. Therefore, the registrant posits that the only importing country on which penthiopyrad would be registered for use on persimmon would be Japan.

C. Revisions to Petitioned-For Tolerances

The Agency is setting a tolerance in or on persimmon of 3 ppm rather than the petitioned-for tolerance value of 3.0 ppm. This value is in accordance with the Organization for Economic

Cooperation and Development (OECD) MRL calculation procedure's rounding class practices.

V. Conclusion

Therefore, tolerances are established for residues of penhiopyrad (*N*-[2-(1,3-dimethylbutyl)-3-thienyl]-1-methyl-3-(trifluoromethyl)-1*H*-pyrazole-4-carboxamide) in or on persimmon at 3 ppm.

VI. Statutory and Executive Order Reviews

This action establishes a tolerance under FFDCA section 408(d) in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled "Regulatory Planning and Review" (58 FR 51735, October 4, 1993). Because this action has been exempted from review under Executive Order 12866, this action is not subject to Executive Order 13211, entitled "Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use" (66 FR 28355, May 22, 2001) or Executive Order 13045, entitled "Protection of Children from Environmental Health Risks and Safety Risks" (62 FR 19885, April 23, 1997), nor is it considered a regulatory action under Executive Order 13771, entitled "Reducing Regulations and Controlling Regulatory Costs" (82 FR 9339, February 3, 2017). This action does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA) (44 U.S.C. 3501 *et seq.*), nor does it require any special considerations under Executive Order 12898, entitled "Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations" (59 FR 7629, February 16, 1994).

Since tolerances and exemptions that are established on the basis of a petition under FFDCA section 408(d), such as the tolerance for residues in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*), do not apply.

This action directly regulates growers, food processors, food handlers, and food retailers, not States or tribes, nor does this action alter the relationships or distribution of power and

responsibilities established by Congress in the preemption provisions of FFDCA section 408(n)(4). As such, the Agency has determined that this action will not have a substantial direct effect on States or Tribal Governments, on the relationship between the National Government and the States or Tribal Governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian Tribes. Thus, the Agency has determined that Executive Order 13132, entitled “Federalism” (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled “Consultation and Coordination with Indian Tribal Governments” (65 FR 67249, November 9, 2000) do not apply to this action. In addition, this action does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act (UMRA) (2 U.S.C. 1501 *et seq.*).

This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act (NTTAA) (15 U.S.C. 272 note).

VII. Congressional Review Act

Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq.*), EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the *Federal Register*. This action is not a “major rule” as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: March 16, 2021.

Marietta Echeverria,

Acting Director, Registration Division, Office of Pesticide Programs.

Therefore, for the reasons stated in the preamble, EPA is amending 40 CFR chapter I as follows:

PART 180—TOLERANCES AND EXEMPTIONS FOR PESTICIDE CHEMICAL RESIDUES IN FOOD

1. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 321(q), 346a and 371.

2. In § 180.658, amend paragraph (a)(1) by designating the table and adding in alphabetical order in newly designated Table 1 to paragraph (a)(1) the entry “Persimmon” and footnote 2 to read as follows:

§ 180.658 Penthiopyrad; tolerances for residues.

(a) * * *
(1) * * *

Table 1 to Paragraph (a)(1)

Commodity	Parts per million
* * * *	* * *
Persimmon ²	3
* * * *	* *

* * * *

²There are no U.S. registrations for this commodity as of [INSERT DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

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[FR Doc. 2021-07129 Filed: 4/6/2021 8:45 am; Publication Date: 4/7/2021]